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10/590,061	11/22/2006	Iris Strodtholz	2955-232	4188

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EXAMINER	
CHUI, MEI PING	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,061	STRODTHOLZ ET AL.	
	Examiner	Art Unit	
	MEI-PING CHUI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date: 08/21/2006, 11/22/2006 and 01/11/2007.

DETAILED ACTION

Status of Action

The Examiner acknowledges receipt of application number 10/590,061 filed on 08/21/2006. Claims 31-32 have been cancelled, and claims 1-30 are presented in this application.

Status of Claims

Claims 1-30 are presented for examination on the merits for patentability.

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 and 14-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 11-13, 16-25 and 27-32 of co-pending U.S. Patent Application No. 10/571,757 (U. S. Patent Application Publication No. 2007/0166337) in view of Philips et al. (U. S. Patent Application Publication No. 2003/0147830).

Although the conflicting claims are not identical, they are not patentably distinct from each other. Instant claim 1 is directed to a skincare composition for treating acne comprising salicylic acid (0.1 % to 5.0 %) and a hydrolyzed milk protein. Conflicting claim 1 of co-pending U.S. Patent Application No. 10/571,757 is also directed to a skincare composition for topical application comprising salicylic acid (0.1 % to 10 %).

Instant and conflicting claims differ in that instant claim 1 recites the composition comprising a hydrolyzed milk protein, whereas conflicting claim 1 does not recite this ingredient. However, the deficiency is cured by the teaching of Philips et al.

Philips et al. teach a topical personal care composition comprising a hydrolyzed protein. Philips et al. teach that the addition of hydrolyzed protein to the composition provides a skin

tightening effect while maintaining good skin feel and good aesthetics (page 1: [0012] and [0018]).

Philips et al. also teach that the hydrolyzed protein can be presented in a safe and effective amount ranging from about 0.0001 % to about 40 % , preferably from about 0.001 % to 5 % by weight of the composition (page 2: [0035]), wherein the hydrolyzed proteins can be milk proteins, β-lactoglobulin or casein (page 3: [0042], lines 1-4). Philips et al. further teach that the composition can be an emulsion, i.e. oil-in-water emulsion or water-in-oil emulsion; and the composition can also comprise optional ingredients, i.e. thickening agents, anti-acne actives (e.g. salicylic acid and benzoyl peroxide) or anti-inflammatory agents (page 6: [0065] and [0109]).

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the conflicting claims of co-pending U.S. Patent Application No. 10/571,757 and the teaching of Philips et al. to arrive at the instant invention.

One of ordinary skill would have been motivated to utilize a hydrolyzed protein in a composition comprising salicylic acid for the purpose of treating acnes because hydrolyzed protein is capable of providing benefits to a skin, i.e. tightening the skin, good skin feel and good aesthetics, as taught by Philips et al. Thus, when the hydrolyzed protein is used in combination with salicylic acid, it can help to provide additional beneficial effects to a skin besides the effects result from salicylic acid.

Therefore, one of ordinary skill in the art, at the time the claimed invention was made, would have readily recognized that claims 1-6, 11-13, 16-25 and 27-32 of co-pending U. S. Patent Application No. 10/571,757 in view of Philips et al. and claims 1-11 and 14-30 in the instant application are obvious variant and are not patentability distinct.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 3, 6, 9 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Claims 6, 9 and 26 are rejected because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "parenthesis" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, **claim 6** recites the broad range of the concentration of hydrolyzed milk protein, which ranges at least 0.05 % by weight; however, claim 6 also recites the concentration of hydrolyzed milk protein is most preferably at least 0.1 % by weight, which is the narrower statement of the range.

Likewise, **claim 9** recites the broad range of the concentration of hydrolyzed milk protein, which ranges at least 0.08 % to 2 % by weight; however, claim 9 also recites the concentration of hydrolyzed milk protein is most preferably at least 0.1 % to 0.5 % by weight, which is the narrower statement of the range.

Claim 26 recites the broad range of the amount of the skincare composition, which the fibrous material is impregnated, is in the range from 10 % to 30 % by weight; however, claim 26 also recites the amount of the skincare composition is preferably in the range from 15 % to 20 % by weight and most preferably is in the range from 18 % to 22 % by weight, which are the narrower statement of the ranges.

(2) **Claim 3** is rejected because it recites a limitation for "the concentration of salicylic acid is at least 1 % by weight, according to claim 2", wherein claim 2 is dependent from claim 1. Since the concentration of salicylic acid is limited to the concentration from 0.1 % to 5 %, as recited in claim 1; therefore, any concentration above 5 % by weight for salicylic acid lacks antecedent basis, and the claim therefore is indefinite.

Likewise, **claim 6** is rejected because it recites a limitation for "the concentration of hydrolyzed milk protein is at least 0.05 % by weight" according to claim 1. Since the concentration of hydrolyzed milk protein is limited to the concentration ratio with salicylic acid, (in which salicylic acid is present in 0.1 % to 5 % by weight) based on the ratio ranges from 2:1 to 15:1 parts by weight as recited in claim 1; therefore, any concentration above 2.5 % by weight for hydrolyzed milk protein lacks antecedent basis, and therefore the claim is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claims 1-19 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (U. S. Patent No. 5,612,324) in view of Philips et al. (U. S. Patent Application Publication No. 2003/0147830).

Applicants Claim

Applicants claim a skincare composition and a method for treating acne comprising salicylic acid (0.1 % to 5.0 %) and hydrolyzed milk protein (0.05 % to 4 %), wherein the pH of the composition is in the range of 2.5 to 6.0. Applicants also claim that the composition further comprises additional agents, i.e. antibacterial agent, thickening agent, excipients, and an article of fibrous material, i.e. cellulose for applying the composition.

Determination of the scope and content of the prior art
(MPEP 2141.01)

Lin et al. teach a method of treating acne in mammalian skin comprising a safe and effective amount of salicylic acid and a pharmaceutical-acceptable carrier (column 2, lines 45-52).

More specifically, Lin et al. teach the composition comprising:

(a) salicylic acid present from about 0.01 % to 20 %, preferably from 0.5 % to 2.0 %, by weight of the composition, which is essential for providing anti-acne benefit and effect on skin via its keratolytic activity (column 3, lines 5-11);

(b) a pH range from about 2 to about 7, preferably 2.5 to 4.5, which is an important for the availability of the salicylic acid and the stability of the composition (column 3, lines 54-57 and column 4, lines 13-17);

(c) additional anti-acne agents, i.e. anti-microbials, anti-bacterials, anti-fungals or anti-virals, i.e. benzoyl peroxide, or anti-inflammatory drugs (column 5, lines 9-24 and 34).

(d) one or more optional components, i.e. humectant/moisturizer/skin conditioner, surfactants, emollients, thickening agents, preservatives for maintaining the antimicrobial integrity, chelators and sequestrants, fragrances, and colorants (column 5 through column 8, line 9).

Lin et al. also teach that the composition can be incorporated into a medicated cleansing pad made of non-woven fabric material (e.g. cellulose-based non-woven), which can be applied topically to mammalian skin for treating acne (column 8, lines 16-21, 60-64; column 11, lines 24-45; Example VIII and lines 59-61).

Lin et al. further teach that the composition comprises a safe and effective amount of a topical pharmaceutical acceptable carrier or diluent, which can be of a variety of different forms and are suitable for topical application to the mammalian skin without causing any unsafe or toxicity concerns, wherein the carrier can be in the form of a hydro-alcoholic system (e.g. liquids or gels), an emulsion system (e.g. oil-in-water or water-in-oil) (column 4, lines 19-35 and column 10: Example VII-gel composition).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Lin et al. do not teach the skincare composition for treating acne comprising hydrolyzed milk protein. However, this deficiency is cured by the teaching of Philips et al.

Philips et al. teach a topical personal care composition comprising at hydrolyzed protein. Philips et al. teach that the addition of hydrolyzed protein to the composition provides a skin tightening effect while maintaining good skin feel and good aesthetics (page 1: [0012] and [0018]).

Philips et al. also teach that the hydrolyzed protein can be presented in a safe and effective amount ranging from about 0.0001 % to about 40 % , preferably from about 0.001 % to 5 % by weight of the composition (page 2: [0035]), wherein the hydrolyzed proteins can be milk proteins, β-lactoglobulin or casein (page 3: [0042], lines 1-4). Philips et al. further teach that the composition can be an emulsion, i.e. oil-in-water emulsion or water-in-oil emulsion; and the composition can also comprise optional ingredients, i.e. thickening agents, anti-acne actives (e.g. salicylic acid and benzoyl peroxide) or anti-inflammatory agents (page 6: [0065] and [0109]).

Finding of prima facie obviousness Rational and Motivation
(MPEP 2142-2143)

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teaching of Lin et al. and Philips et al. to arrive at the instant invention.

One of ordinary skill would have been motivated to utilize a hydrolyzed protein in a composition comprising salicylic acid for the purpose of treating acnes because hydrolyzed protein is capable of providing benefits to a skin, i.e. tightening the skin, good skin feel and good aesthetics, as taught by Philips et al. Thus, when the hydrolyzed protein is used in combination with salicylic acid, it can help to provide additional beneficial effects to a skin besides the effects result from salicylic acid.

In the absence of evidence to the contrary, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

(2) Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (U. S. Patent No. 5,612,324) and Philips et al. (U. S. Patent Application Publication No. 2003/0147830) in combination, further in view of Suares et al. (WO 02/022236 A1).

Applicants Claim

Applicants claim a skincare composition comprising salicylic acid (0.1 % to 5.0 %), a hydrolyzed milk protein and a gelling agent, i.e. a copolymer of acryloyl dimethyl tauric acid or a salt thereof; wherein the pH of the composition is in the range of 2.5 to 6.0.

Determination of the scope and content of the prior art (MPEP 2141.01)

The combined teaching of Lin et al. and Philips et al. have been set forth above. Essentially, Lin et al. teach a composition, for treating acne in mammalian skin, comprising salicylic acid and at least one optional component, wherein the composition has a pH value range from about 2 to about 7. Philips et al. teach a topical personal care composition comprising a hydrolyzed protein from milk source, which can provide benefits, i.e. skin tightening effect, good skin feel and good aesthetics.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

However, Lin et al. and Philips et al. do not teach the composition comprising a copolymer of acryloyl dimethyl tauric acid or a salt thereof as a gelling agent. This deficiency is cured by the teaching of Suares et al.

Suares et al. teach an improved thickening system that is effective at low pH, i.e. less than 6, for cosmetic compositions to overcome the existing problems in that some formulations are extremely difficult to thicken, especially the formulations that have low pH systems are particularly sensitive and difficult. Even if initially thickened, those formulations may have storage stability problems (page 2: 1-13 and page 1, lines 3-5).

Suares et al. teach that the thickening system provides a thickened effect to the composition with sufficient aesthetical pleasing viscosity and skinfeel. Suares et al. also teach that the thickening system is suitable for water and oil emulsion cosmetic compositions, and the thickeners in the system function as stabilizers by preventing phase separation (page 2: lines 18-21).

Suares et al. further teach the thickening agents are taurate copolymers that are highly effective for low pH cosmetic compositions (page 7, lines 7-9). This system is particularly useful for building viscosity in relatively acidic compositions, at the same time, stabilizing oil and water emulsions, and providing a good skin feel (page 3, lines 1-13). A particularly useful taurate copolymer is acryloyl dimethyl taurate (in either free acid or salt form) (page 3, lines 14-18 and page 18, claim 3).

Finding of prima facie obviousness Rational and Motivation (MPEP 2142-2143)

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teaching of Lin et al. and Philips et al., and further in view of Suares et al. to arrive at the instant invention.

One of ordinary skill would have been motivated to choose a specific thickening agent, i.e. a copolymer of acryloyl dimethyl taurate (in either free acid or salt form), because the copolymer of acryloyl dimethyl taurate is an effective thickening agent suitable for use cosmetic composition that has low pH, as taught by Suares et al.

From the teaching of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention,

as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. C./

Examiner, Art Unit 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616